# Electronic Data Capture into e-Case Report Forms

**Issues of Implementation and the FDA**

**Jeff Smith/CBER**

*{reference to Dr. Woodcock- "ultimate goal"}*
*{speak- working group and committee history}*
*{speak- agency wide initiative at the Compliance program management level, BIMO}*

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## What is Electronic Data Capture into e-CRFs ?

The use of an electronic device/software that enables a physician or physician's assistant to enter patient data directly into an electronic Case Report Form, its content being maintained in an electronic database.

- ❖ The source data may be electronic.
- ❖ Submission to FDA of e-CRFs is not at issue here.

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## Impetus for the Use of Electronic Data Capture

*{reference to Dr. Zoon and David Isom's talk}*
*{document room size; pending e-sig rule; paper reduction; cost savings?}*

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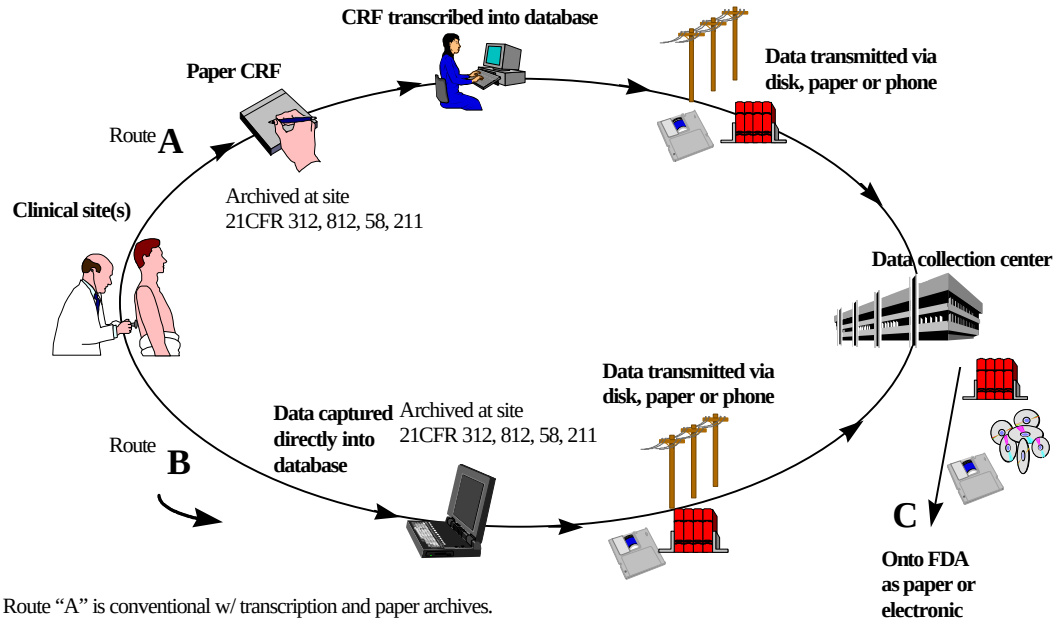
# Paper CRF verses e-CRF

*{graphic of data capture into CRFs below- explain, focus on element at issue}*




Route "A" is conventional w/ transcription and paper archives.

Route "B" is electronic capture and focus of guidance w/ NO transcription and WITH electronic archives.

Route "C" has been the focus of other initiatives in FDA, receipt of e-submissions including e-CRFs.

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# The Element at Issue
# Pertinent Changes/Issues

- Data is captured directly into a database
  - No transcription
  - Authentication issues *(e-signature requirements)*
  - Audit trail issues
- No paper Case Report Form exists
  - Electronic data may be source data
  - Inspectional issues
  - Archiving issues
  - Tool is now required to view records
- Additional Regs Now Apply as Data Captured Electronically
  - e-Signature Proposed Rule 21 CFR part 11 (59 FR 45160)

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# Issues & Appropriate References

- **Archiving**
  - Time: 58.195(c); 312.57-62; 812.140
  - Accessible: 58.190(b,d,e); 211.180(c); 36CFR1234.28
  - Inspection: 211s; 312.58; 312.68; 812.145
- **Security/privacy:** 50.25(c)(5); 36CFR1234.26
- **Authentication:** 59 FR 45160; 11; 36CFR1234.24
- **Data Integrity:** ICH Docket # 95D 0219
- **Verification:** FDA technical report "Software Development Activities, 1987- Document predetermined criteria; Written test plan; Test results & interpretation.
- **Do we / how do we offer "guidance":** 61 FR 9181

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# Specific Subjects and Ideas Discussed at the BIMO Working Group

*{speak on current issues discussed}*
*{examples of rational and underlying complexities}*

# Conclusion